

# INS

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## INTRAVENOUS NURSES SOCIETY

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August 19, 1999

Dr. Jane E. Henney, Commissioner  
Dockets Management Branch  
Reading Room 1061  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane  
Rockville, MD 20857

Dear Dr. Henney:

The Intravenous Nurses Society (INS) is a national nonprofit member organization founded in 1973. INS is the largest organization for the intravenous (IV) specialty and exists to promote excellence in intravenous nursing through standards, education, public awareness and research. INS is concerned about the inherent dangers involved in administering intravenous therapy with respect to the extent of human exposure and potential health risks associated with di-ethylhexyl-phthalate (DEHP). DEHP is the primary phthalate plasticizer used to make PVC medical devices, such as blood bags, intravenous bags and medical tubing, soft and flexible. Studies indicate that since DEHP is not chemically bound to the polymer in PVC, it can leach out into the fluid contained within the medical devices and enter the patient's bloodstream.

Cancer drugs Taxol and Taxotere and other medications with formulations that accelerate the leaching of DEHP presently carry warnings against using PVC bags or tubing for their administration. The FDA limits the amount of plasticizer to no more than 30 per cent of materials content in food containers; PVC medical products used to contain blood and intravenous solutions all contain more than 30 per cent plasticizer by weight. INS suggests that the FDA mandate a Taxol-like warning for PVC medical products containing DEHP.

Therefore, the Intravenous Nurses Society supports the Health Care Without Harm's Citizen Petition (Docket 99P-2077) for a Food and Drug Administration Regulation or Guideline to Label Medical Devices That Leach Phthalate Plasticizers and to Establish a Program to Promote Alternatives.

Sincerely,

*Mary Alexander*

99P-2077

Mary Alexander, RN,CRNI  
Chief Executive Officer

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